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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,954	06/21/2001	Maureen J. Charron	96700/667	6743

7590

03/25/2005

Craig J. Arnold, Esq.
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New York, NY 10016

EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/886,954

Applicant(s)

CHARRON ET AL.

Examiner

Gary B. Nickol Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 6-11 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11 and 16-20 is/are allowed.
- 6) ☒ Claim(s) 1 and 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: (Sequence Comparison).

Art Unit: 1642

Re: Charron *et al.*

Date of priority: June 21, 2001

Response to Amendment

The Amendment filed 12-13-04 in response to the Office Action of 10-05-2004 is acknowledged and has been entered.

Claims 1, 6-11, 16-20 are pending and are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

New Rejection:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, and 6-10 are rejected under 35 U.S.C. 102(e) as being anticipated by WO

01/90304 A2 (Human Genome Sciences, Inc, May 2000).

WO 01/90304 A2 teaches an isolated clone (HEGAC86, see page 514, SEQ ID NO:2091) that encodes a polypeptide having 61% identity to the claimed GLUTx protein (see attached sequence listing comparison).

The reference further teaches diagnostic assays and methods for determining whether a subject has a defect in cell proliferation comprising assaying a diagnostic sample of the subject for any of the disclosed genes (pages 1832-1841) including wherein the diagnostic sample is assayed using labeled antibodies or labeled nucleic acid probes and wherein the detection of the inventive genes or polypeptides is elevated above normal (see para 0391, page 1840). The reference further teaches that the polypeptides and polynucleotides disclosed can be used to detect certain hyperproliferative disorders including cancers of the breast and endometrium (pages 1878-1879).

Hence, the claimed method is anticipated because the labeled nucleic acid probes and or labeled antibodies of the prior art would *inherently* cross-react with a GLUTx protein that has the amino acid of SEQ ID NO:1. The steps of the claimed methods are identical to the prior art method and the product of the prior art is substantially identical to the GLUTx protein. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

Art Unit: 1642

Claims 11, and 16-20 appear allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

GBN



**GARY NICKOL
PRIMARY EXAMINER**

QY 121 WMLLGRLLTGLACGVAISHVAPVYISEIAPAVRGLGSCVOLMWWVGIILAYLAGWYLE 180
 Db 74 -----VYISEIAPAVRGLGSCVOLMWWVGIILAYLAGWYLE 111
 QY 181 WRMLAVLGCVPSPIMLLMCMFETPRFLLTOHROBAMAAALFLMGSEQMEDPPIGAE 240
 Db 112 WRMLAVLGCVPSPIMLLMCMFETPRFLLTOHROBAMAAALFLMGSEQMEDPPIGAE 171
 QY 241 QSFHLLALRQPGIYKFFIIIGVSLMAQOLSGVNAWVFYATETIPEEKFKDSSIASVVG 300
 Db 172 -----QOLSGVNAWVFYATETIPEEKFKDSSIASVVG 205
 QY 301 IOVLFTVAALIMDRAGRLLLVLSGVVWFSTARGAEFKLTGGAGNSHVATSAAPS 360
 Db 206 IOVLFTVAALIMDRAGRLLLVLSGVVWFSTARGAEFKLTGGAGNSHVATSAAPS 265
 QY 361 AOPVDAVGLAMLVANGSMLCFLTAGFAVWGPIPMILMSIIFPLHVGVAATGICVLTNMLM 420
 Db 266 AOPVDAVGLAMLVANGSMLCFLTAGFAVWGPIPMILMSIIFPLHVGVAATGICVLTNMLM 325
 QY 421 AFLVTKESPESLMEVLRPYGAFWMLASFCIESVLEFLLFCVPERKGTLEQITAHFGR 477
 Db 326 AFLVTKESPESLMEVLRPYGAFWMLASFCIESVLEFLLFCVPERKGTLEQITAHFGR 382

RESULT 9
 ADL33342
 ID ADL33342 standard; protein; 353 AA.

AC ADL33342;
 DT 20-MAY-2004 (first entry)
 DE Human transporter and ion channel (TRICH) protein #46.

XX anti-HIV; antiallergic; antiinflammatory; antianemic; antiparkinsonian;
 KW immunosuppressive; anticonvulsant; antiarteriosclerotic; antidiabetic;
 KW antidiabetic; atheroprotective; antihypertensive; antineoplastic; antiparasitic;
 KW osteoporosis; osteoarthritis; osteoporosis; osteoporosis; osteoporosis;
 KW uropathic; ophthalmological; antineumatic; hemostatic; antibacterial;
 KW virucide; protozoicide; fungicide; gene therapy.

OS Homo sapiens.
 PN WO2003083085-A2.
 PD 09-OCT-2003.
 PP 27-MAR-2003; 2003WO-US009797.
 XX 28-MAR-2002; 2002US-0368840P.
 PR 26-APR-2002; 2002US-0375637P.
 XX (INCY-) INCYTE CORP.

PI Marquis JP, Lee SY, Emerling BM, Hafalia AUA, Khare R, Kable AE,
 PI Richardson TM, Swannaker A, Chawla NK, Becha SP, Mason PM;
 PI Elliott VS, Rankumar J, Griffin JA, Tran UK, Ison CH, Lindquist EA,
 PI Jiang X, Jackson AA, Wilson AD, Jin P, Chang H;
 DR WPI; 2003-833535/77.
 DR N-PSDB; ADL33401.

PT New human transporters and ion channels (TRICH) and polynucleotides,
 PT useful for diagnosing, treating or preventing autoimmune or inflammatory
 PT disorders (e.g. AIDS, allergy or anemia), multiple sclerosis, cancer or
 PT hepatitis.

PS Claim 1; SEQ ID NO 46; 405bp; English.

CC The invention relates to an isolated polypeptide (I), which is a human
 CC intracellular signaling molecule, which is a human intracellular

CC signaling molecule, a naturally occurring amino acid sequence at least 90%
 CC identical to it or a biologically active fragment or an immunogenic
 CC fragment of the polypeptide. The human TRICH, polynucleotides, agonists
 CC and antagonists are useful for diagnosing, treating or preventing
 CC disorders associated with aberrant expression of TRICH, particularly cell
 CC proliferative disorders (e.g. arteriosclerosis, atherosclerosis,
 CC cirrhosis, hepatitis, paroxysmal nocturnal hemoglobinuria, polycythemia
 CC vera, psoriasis, primary thrombocytopenia or cancer), developmental
 CC disorders (e.g. renal tubular acidosis, anemia or mental retardation),
 CC neurological disorders (e.g. Alzheimer's disease, Parkinson's disease or
 CC epilepsy), autoimmune/inflammatory disorders (e.g. AIDS, allergies,
 CC asthma, autoimmune thyroiditis, contact dermatitis, Crohn's disease,
 CC diabetes mellitus, glomerulonephritis, Goodpasture's syndrome, gout,
 CC Graves' disease, Hashimoto's thyroiditis, irritable bowel syndrome,
 CC multiple sclerosis, osteoarthritis, osteoporosis, pancreatitis, Reiter's
 CC syndrome, rheumatoid arthritis, Sjogren's syndrome, uveitis) or viral;
 CC bacterial, fungal, parasitic, protozoan or helminthic infections. The
 CC polynucleotides encoding TRICH are useful for creating transgenic animals
 CC to model human disease. This sequence corresponds to one of the proteins
 CC of the invention.

CC Sequence 353 AA;

Query Match 67.7%; Score 1664; DB 7; Length 353;
 Best Local Similarity 100.0%; Pred. No. 8e-151;
 Matches 326; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY 1 MTPEDPETOPLGPPGSAAPRGRRVLAFAAALGPLSGFALGYSSPAIPSLORAPP 60
 Db 1 MTPEDPETOPLGPPGSAAPRGRRVLAFAAALGPLSGFALGYSSPAIPSLORAPP 60
 QY 61 APRDDAAASWFGAVVTGLAAAGVGLGMLVDRAGRLSLLGCVPPVAGFAVITAQDV 120
 Db 61 APRDDAAASWFGAVVTGLAAAGVGLGMLVDRAGRLSLLGCVPPVAGFAVITAQDV 120
 QY 121 WMLLGRLLTGLACGVAISHVAPVYISEIAPAVRGLGSCVOLMWWVGIILAYLAGWYLE 180
 Db 121 WMLLGRLLTGLACGVAISHVAPVYISEIAPAVRGLGSCVOLMWWVGIILAYLAGWYLE 180
 QY 181 WRMLAVLGCVPSPIMLLMCMFETPRFLLTOHROBAMAAALFLMGSEQMEDPPIGAE 240
 Db 181 WRMLAVLGCVPSPIMLLMCMFETPRFLLTOHROBAMAAALFLMGSEQMEDPPIGAE 240
 QY 241 QSFHLLALRQPGIYKFFIIIGVSLMAQOLSGVNAWVFYATETIPEEKFKDSSIASVVG 300
 Db 241 QSFHLLALRQPGIYKFFIIIGVSLMAQOLSGVNAWVFYATETIPEEKFKDSSIASVVG 300
 QY 301 IOVLFTVAALIMDRAGRLLLVLSGVVWFSTARGAEFKLTGGAGNSHVATSAAPS 360
 Db 301 IOVLFTVAALIMDRAGRLLLVLSGVVWFSTARGAEFKLTGGAGNSHVATSAAPS 360

RESULT 10
 ABB89717
 ID ABB89717 standard; protein; 326 AA.

AC ABB89717;

DT 24-MAY-2002 (first entry)

DE Human polypeptide SEQ ID NO 2093.

XX Cytostatic; immunosuppressive; neurotropic; neuroprotective; antiviral;
 KW antiallergic; hepatotropic; antidiabetic; antiinflammatory; anticancer;
 KW vulnery; anticonvulsant; antibacterial; antifungal; antiparasitic;
 KW cardiant; gene therapy; cancer; immune disorder; cardiovascular disorder;
 KW neurological disease; infection; human; secreted protein.

OS Homo sapiens.

PN WO200190304-A2.

PD 29-NOV-2001.

XX 18-MAY-2001; 2001MO-US016450.
 XX 19-MAY-2000; 2000US-020551SP.
 XX (HUMA-) HUMAN GENOME SCI INC.
 XX Blaise CE, Rosen CA;
 XX MPI: 2002-122018/16.
 XX N-PSDB; ABL90126.
 XX Novel 1405 isolated polypeptides, useful for diagnosis, treatment and prevention of neural, immune system, muscular, reproductive, gastrointestinal, pulmonary, cardiovascular, renal and proliferative disorders.
 XX Claim 11: SEQ ID NO 2093 2081pp + Sequence Listing; English.
 XX The invention relates to novel genes (AB089449-AB090853) and proteins (AB089440-AB090444) useful for preventing, treating or ameliorating medical conditions e.g. by protein or gene therapy. The genes are isolated from a range of human tissues disclosed in the specification. The nucleic acids, proteins, antibodies and (ant)agonists are useful in the diagnosis, treatment and prevention of: (a) cancer, e.g. breast and ovarian cancer and other cancers of the adrenal gland, bone, bone marrow, breast, gastrointestinal tract, liver, lung, or urogenital; (b) immune disorders e.g. Addison's disease, allergies, autoimmune haemolytic anaemia, autoimmune thyroiditis, diabetes mellitus, Crohn's disease, multiple sclerosis, rheumatoid arthritis and ulcerative colitis; (c) cardiovascular disorders such as myocardial ischaemia; (d) wound healing; (e) neurological diseases such as viral, bacterial, fungal and parasitic infections. Note: The sequence data for this patent did not form part of the printed specification, but was obtained in electronic format directly from WIPO at http://wipo.int/pub/published_pct_sequences

Sequence 326 AA;

Query Match 60.7%; Score 1491; DB 5; Length 326;
 Best Local Similarity 96.3%; Pred. No. 2.9e-134;
 Matches 289; Conservative 1; Mismatches 10; Indels 0; Gaps 0;

QY 164 MVVVGILLAYLAGWLEWRMLAVLGCVPSLMLMCMPEPFLTLQHRROEMALR 223
 DB 1 MVVVGILLAYLAGWLEWRMLAVLGCVPSLMLMCMPEPFLTLQHRROEMALR 60
 QY 224 FLWGEQGEWDEPPIGAESFHLALRQGIYPPITIGVSLMAFQOLSGVNAVMEYATIF 283
 DB 61 FLWGEQGEWDEPPIGXESFHLALRQGIYPPITIGVSLMAFQOLSGVNAVMEYATIF 120
 QY 284 EEAKEKSSLASVVGIVQVFTFAVALIMRAGRLLVLSGVVWVSTAFAGYFRLT 343
 DB 121 EEAKEKSSLASVVGIVQVFTFAVALIMRAGRLLVLSGVVWVSTAFAGYFRLT 180
 QY 344 QGGFQNSSHVAISAPVSAQPYDASVGLAMLVGSGMCFIAGFVAGMGIPMLLSEIFPL 403
 DB 181 QGGFQNSSHVAISAPVSAQPYDASVGLAMLVGSGMCFIAGFVAGMGIPMLLSEIFPL 240
 QY 404 HVKGVATGICVLTWMLAFVLTKEPSSIMELRYGAFWLASAPCISVLTFLCVETK 463
 DB 241 HVKGVATGICVLTWMLAFVLTKEPSSIMELRYGAFWLASAPCISVLTFLCVETK 300

RESULT 11

AA06579 ID AAE06579 standard; protein, 262 AA.
 AC AAE06579;
 XX 25-SEP-2001 (first entry)
 XX Human protein having hydrophobic domain, HP10784.

XX Human; hydrophobic domain; gene therapy; nutritional supplement;
 KW cell proliferation; immunomodulatory; autoimmune disorder; antimicrobial;
 KW multiple sclerosis; rheumatoid arthritis; insulin-dependent diabetes;
 KW haemopoiesis; tissue growth activity; Parkinson's disease; cytostatic;
 KW Huntington's disease; Alzheimer's disease; chemokine; chemokine;
 KW haemostatic; thrombolytic; tumour growth inhibitor; anabolic;
 KW contraceptive; antifertility; antiinflammatory.
 XX Homo sapiens.
 XX WO200149728-A2.
 XX 12-JUL-2001.
 XX 28-DEC-2000; 2000WO-JP09359.
 XX 06-JAN-2000; 2000JP-00000585.
 XX 11-JAN-2000; 2000JP-00000588.
 XX 03-FEB-2000; 2000JP-00026299.
 XX 03-MAR-2000; 2000JP-00058367.
 XX (PROT-) PROTEGENE INC.
 XX (SAGA) SAGAMI CHEM RES CENT.
 XX Kato S, Kimura T;
 XX MPI: 2001-418355/44.
 XX N-PSDB; AAD12574.
 XX Human proteins with hydrophobic domains and the nucleic acids encoding them, useful for preventing diagnosing and treating e.g. cancer, Alzheimer's and inflammation.
 XX Claim 1; Page 75; 563pp; English.

CC The present sequence is human protein with hydrophobic domain, HP10784.
 CC The polynucleotide and polypeptide of the invention may be used in the prevention, diagnosis and treatment of diseases associated with
 CC inappropriate polypeptide expression. The polynucleotides may be used to produce the polypeptide, by inserting the nucleic acids into a host cell and culturing the cell to express the protein. The polynucleotides and its complementary sequences may also be used as DNA probes in diagnostic assays and also used in gene therapy. The polypeptides may also be used as antigens in the production of antibodies and in assays to identify
 CC modulators of polypeptide expression and activity. The polypeptides and nucleic acids may be used as nutritional supplements, to modulate
 CC cytokine and cell proliferation activity, to modulate immune stimulation or suppression (e.g. for the treatment of microbial infections and
 CC autoimmune disorders such as multiple sclerosis, rheumatoid arthritis and insulin-dependent diabetes), to modulate haemopoiesis, to modulate
 CC tissue growth activity (e.g. for the treatment of Parkinson's disease, Huntington's disease and Alzheimer's disease), to modulate actin and
 CC inhibit activity (e.g. for controlling fertility), to modulate
 CC chemotactic and chemokinetic activity, to modulate haemostatic and
 CC thrombolytic activity, to modulate receptor ligand activity, to modulate
 CC inflammatory activity and to inhibit tumour growth

Sequence 262 AA;

Query Match 46.2%; Score 1135; DB 4; Length 262;
 Best Local Similarity 91.4%; Pred. No. 3.3e-100;
 Matches 223; Conservative 2; Mismatches 7; Indels 12; Gaps 1;

QY 1 MTPEDPEETOPPLGPGGAPRGVFAAFAAALGPTSGFAGLYSSPAIPSORAPP 60
 DB 1 MTPEDPEETOPPLGPGGAPRGVFAAFAAALGPTSGFAGLYSSPAIPSORAPP 60
 QY 61 APRLDAAASWFGAVVTLGAAGVTLGGLVDRAGRKSLILGCVFPVAGRAVITAQDV 120
 DB 61 APRLDAAASWFGAVVTLGAAGVTLGGLVDRAGRKSLILGCVFPVAGRAVITAQDV 120